

## Actions Taken by FDA Center for Veterinary Medicine

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The following corrections or additions to the January 2004 list were published in the Federal Register in December 2003.

### New Approvals

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**ANADA Number: 200-308**

Pioneer Product: 101-479  
Trade Name: Flunixin Injection  
Ingredients: Flunixin meglumine  
Sponsor: Norbrook Laboratories, Ltd.  
Approval Date: November 17, 2003  
Status: Prescription only  
Route: Intravenous, intramuscular  
Species: Horses, cattle (beef and non-lactating dairy heifers)  
Drug Form: Liquid (solution)  
Concentration: 50 milligrams per milliliter  
Indications: For the alleviation of inflammation and pain associated with musculoskeletal disorders, and the visceral pain associated with colic in horses. In cattle it is indicated for the control of pyrexia associated with bovine respiratory disease and endotoxemia and for the control of inflammation in endotoxemia.  
Tolerance: 21CFR 556.286 Flunixin meglumine: For residues of parent flunixin free acid of 0.125 part per million in cattle liver (target tissue) and 0.025 part per million in cattle muscle are established.  
Withdrawal: Cattle - 4 days

*21CFR 522.970*

**NADA Number: 141-219**

Trade Name: Metacam<sup>®</sup>  
Ingredients: Meloxicam  
Sponsor: Boehringer Ingelheim Vetmedica, Inc.  
Approval Date: November 12, 2003  
Status: Prescription only  
Route: Intravenous or subcutaneous  
Species: Dogs  
Drug Form: Liquid (solution)  
Concentration: 5 milligrams per milliliter  
Indications: For the control of pain and inflammation associated with osteoarthritis.  
Exclusivity: 3 years

*21CFR 522.1367*

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### Supplemental Approvals

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This section displays the change(s) to the original approval. To read the complete approval please refer to *21CFR Parts 500* and related Federal Register notices.

**NADA Number: 200-247**

**This supplemental application provides for the additional use in new species, honey bees, a reduction in preslaughter withdrawal time in swine, and a new container size.**

Trade Name: Oxytetracycline HCl Soluble Powder - 343  
Ingredients: Oxytetracycline Hydrochloride  
Sponsor: Phoenix Scientific, Inc.  
Approval Date: November 12, 2003  
Status: Over-the-counter  
Route: Oral, via feed  
Species: Swine, honey bees  
Drug Form: Powder  
Concentration: 343 grams per pound  
Indications: Honey bees: Control and treatment of American and European foul brood caused by *Bacillus spp.* larvae susceptible to oxytetracycline.  
Swine: Control and treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida*.  
Tolerance: 21CFR 556.500 Oxytetracycline: Tolerances are established for the sum of residues in tissues and milk for beef cattle, dairy cattle, calves, swine, sheep, chickens, turkeys, catfish, lobsters, and salmonids as follows: 6 parts per million in liver, 12 parts per million in fat and kidney, and 0.3 part per million in milk.  
Withdrawal: Swine - zero days  
Honey bees - 6 weeks prior to main honey flow.

*21CFR 520.1660d*

### Removal of a Patent Number

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**NADA Number: 140-845**

Patent Number: 4,764,534      Expiration Date: August 15, 2005

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### Suitability Petition Action

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Number:	03P-0469/CP1
Sponsor:	Eugene G. Keller
Petition:	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan <sup>®</sup> Paste, Merial Ltd., NADA 134-314 by the following characteristics: The generic product will have a different strength and dosage form from the pioneer.
Action:	Approved on December 4, 2003.
Number:	03P-0523/CP1
Sponsor:	Karen A. Sisson
Petition:	Request permission to file an ANADA for a generic new animal drug ivermectin/praziquantel which differs from the pioneer product, ivermectin/praziquantel (Zimecterin <sup>®</sup> Gold Paste), Merial Ltd., NADA 141-214 by the following characteristics: The generic product will consist of a different dosage form (granule/crumble) from the pioneer.
Action:	Approved on December 4, 2003.
Number:	03P-0552/CP1
Sponsor:	Jurox PTY, Limited
Petition:	Request permission to file an ANADA for a generic new animal drug carprofen which differs from the pioneer product, Rimadyl <sup>®</sup> Caplets, Pfizer, Inc., NADA 141-053 by the following characteristics: The generic product will have a different dosage form (liquid) and different strength from the pioneer.
Action:	Filed on December 10, 2003.

## **Actions Taken by FDA Center for Veterinary Medicine**

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